



BAU: 1655\$

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

7-27  
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Applicants: Soderlund *et al.*

Examiner: Myers, C.

Serial No.: 08/465,322

Group Art Unit: 1655

Filed: June 5, 1995

Docket: 13025-4

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For: METHOD AND REAGENT FOR DETERMINING  
SPECIFIC NUCLEOTIDE VARIATIONS

Kalow & Springut LLP  
488 Madison Avenue, 19th Floor  
New York, New York 10022

June 29, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Attorneys for the Applicants acknowledge receipt of an Office Action (Paper No. 26) dated June 19, 2000 which withdraws the finality of the previous Office Action. Applicants submit herewith the following disclosures in accordance with the provisions of 37 CFR § 1.97 and § 1.98.

US PATENT DOCUMENTS

<u>PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
4,307,189 to Kit	Method for the Quantitative Determination of Terminal Deoxynucleotidyl Transferase in Biological Samples	December 22, 1981

\*These references are not enclosed as they were provided in parent application 08/162,376 and are already of record. (37 CFR § 1.98(d)).

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<u>PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
4,563,419 to Ranki <i>et al.</i>	Detection of Microbial Nucleic Acids By a One-Step Sandwich Hybridization Test	January 7, 1986
4,683,195 to Mullis <i>et al.</i>	Process for Amplifying, Detecting and/or Cloning Nucleic Acid Sequences	July 28, 1987
4,883,750 to Whiteley <i>et al.</i>	Detection of Specific Sequences in Nucleic Acids	November 28, 1989
4,962,020 to Tabor <i>et al.</i>	DNA Sequencing	October 9, 1990
4,968,602 to Dattagupta	Solution-Phase Single Hybridization Assay For Detecting Polynucleotide Sequences	November 6, 1990

**FOREIGN PATENT DOCUMENTS**

<u>DOCUMENT NO.</u>	<u>TITLE</u>	<u>PUBLICATION DATE</u>
GB 2,202,328	An Improved Method for Assaying of Nucleic Acids, a Reagent Combination and a Kit Therefore	21 September 1988
WO 86/03782	Improved Sandwich Hybridisation Technique for the Detection of Nucleotide Sequences	3 July 1986
WO 89/09282	Method of Sequencing DNA	5 October 1989
WO 89/10414	Amplified Sequence Polymorphisms (ASPs)	2 November 1989
WO 90/01069	Process for Amplifying and Detecting Nucleic Acid Sequences	8 February 1990

\*These references are not enclosed as they were provided in parent application 08/162,376 and are already of record. (37 CFR §1.98(d)).

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<u>DOCUMENT NO.</u>	<u>TITLE</u>	<u>PUBLICATION DATE</u>
WO 90/06042	Detection and Quantitative Determination of RNA and DNA	14 June 1990
*WO 90/11372	Multiplex DNA Diagnostic Test	4 October 1990
EP 0238332	Liquid Hybridization Method and Kit for Detecting the Presence of Nucleic Acid Sequences in Samples	23 September 1987
EP 0246864	Hybridisation Probes	25 November 1987
EP 0288737	Rapid Hybridization Assay Using Latex-Immobilized Probes	2 November 1988
EP 0297379	Assay of Sequences Using Amplified Genes	4 January 1989
EP 0317074	Hybridization Method and Reagent Kit Therefor	24 May 1989
EP 0333465	Mutation Detection by Competitive Oligonucleotide Priming	20 September 1989
EP 0357011	Detection and Amplification of Target Nucleic Acid Sequences	7 March 1990
EP 0370694	Diagnostic Kit and Method Using a Solis Phase Capture Means for Detecting Nucleic Acids	30 May 1990
EP 0371437	Method and Reagent Combination for Determining Nucleotide Sequences	6 June 1990

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**DOCUMENT**  
**NO.**

**TITLE**

**PUBLICATION**  
**DATE**

*EP 0412883	Fast Process for Detecting and/or Identifying a Single Base on a Nucleic Acid Sequence and Its Applications	13 February 1991
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**OTHER DOCUMENTS**

1. Syvanen et al., "Direct Sequence of Affinity-Captured Amplified Human DNA Application to the Detection of Apolipoprotein E Polymorphism", FEBS Letters, 258:71-74 (1989).
2. Syvanen et al., "Quantification of Polymerase Chain Reaction Products by Affinity-Based Hybrid Collection," Nucleic Acids Research, 16:11327-11339 (1988).
3. Ballabio et al., "PCR Test for Cystic Fibrosis Deletion", Nature, 343:220 (1990).
4. Grimberg et al., "A Simple and Efficient Non-Organic Procedure for the Isolation of Genomic DNA From Blood", Nucleic Acids Research, 17:8390 (1989).
5. Signer et al., "DNA Fingerprinting: Improved DNA Extraction From Small Blood Samples", Nucleic Acids Research, 16:7738 (1988).
6. Signer et al., "Modified Gel Electrophoresis for Higher Resolution of DNA Fingerprints", Nucleic Acids Research, 16:7739 (1988).
7. Mitchell et al., "Affinity Generation of Single Stranded DNA Following the Polymerase Chain Reaction: Application to Dideoxy Sequencing", WH 214 Journal of Cellular Biochemistry Supp. 13E 18<sup>th</sup> Annual Meeting (1989).

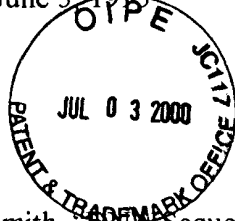
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8. Smith, "DNA Sequence Analysis by Primed Synthesis", *Methods in Enzymology*, 65:560-581 (1980).
9. Kuppuswamy et al., "A New Use of Polymerase Chain Reaction (PCR) in Carrier Detection of Hemophilia-B Due to Point Mutations", *Blood*, The Journal of the American Society of Hematology, Thirty-First Annual Meeting of the American Society of Hematology, 74:957 (1989).
10. Rommens et al., "Identification of the Cystic Fibrosis Gene: Chromosome Walking and Jumping", *Science*, 245:1059-1065 (1989).
11. Riordan et al., "Identification of the Cystic Fibrosis Gene: Cloning and Characterization of Complementary DNA", *Science*, 245:1066-1072 (1989).
12. Wu et al., "Allele-specific Enzymatic Amplification of  $\beta$ -Globin Genomic DNA for Diagnosis of Sickle Cell Anemia", *Proc. Natl. Acad. Sci. USA*, 86:2757-2760 (1989).
13. Newton et al., "Analysis of Any Point Mutation in DNA. The Amplification Refractory Mutation System (ARMS)", *Nucleic Acids Research*, 17:2503-2516 (1989).
14. Ehlen et al., "Detection of Ras Point Mutations by Polymerase Chain Reaction Using Mutation-Specific Inosine-Containing Oligonucleotide Primers", *Biochemical and Biophysical Research Communications*, 160: 441-447 (1989).
15. Nassal et al., "PCR-Based Site-Directed Mutagenesis Using Primers With Mismatched 3' - Ends", *Nucleic Acids Research*, 18:3077-3078 (1990).
16. Caskey et al., "Disease Diagnosis by Recombinant DNA Methods", *Science*, 236:1223-1228 (1987).
17. Landegren et al., "DNA Diagnostics - Molecular Techniques and Automation", *Science*, 242:229-237 (1988).
18. Rossiter et al., "Molecular Scanning Methods of Mutation Detection", *The Journal of Biological Chemistry*, 265:12753-12756 (1990).

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19. Spitzer et al., "Replacement of Isoleucine-397 by Threonine in the Clotting Proteinase Factor IXa (Los Angeles and Long Beach Variants) Affects Macromolecular Catalysis but not L-tosylarginine Methyl Ester Hydrolysis", *Biochem. J.* 265: 219-225 (1990).
20. Kuppaswamy et al., "Single Nucleotide Primer Extension to Detect Genetic Diseases: Experimental Application to Hemophilia B (factor IX) and Cystic Fibrosis Genes", *Proc. Natl. Acad. Sci. USA*, 88:1143-1147 (1991).
21. Prober et al., "A System for Rapid DNA Sequencing With Fluorescent Chain-Terminating Dideoxynucleotides", *Science*, 238:336-341 (1987).
22. Landegren et al., "A Ligase-Mediated Gene Detection Technique", *Science*, 241:1077-1080 (1988).
23. Mikita et al., "Functional Consequences of the Arabinosylcytosine Structural Lesion in DNA", *Biochemistry*, 27:4698-4705 (1988).
24. Mullis et al., "Specific Synthesis of DNA in Vitro Via a Polymerase-Catalyzed Chain Reaction", *Methods in Enzymology*, 155:335-351 (1987).
25. Spitzer et al., "Molecular Defect in Factor IX<sub>Bm Lake Elsinore</sub>", *The Journal of Biological Chemistry*, 263:10545-10548 (1988).
26. Ware et al., "Genetic Defect Responsible for the Dysfunctional Protein: Factor IX<sub>Long Beach</sub>", *Blood*, 72:820-822 (1988).

The above documents are also listed on Applicants' PTO 1449 Form which is enclosed for the convenience of the Examiner. A copy of each of the items identified above which does not have an asterisk is submitted with this statement.

The attorneys for the Applicants take no position on whether or not any item cited above and listed on Form PTO 1449 constitutes prior art against the subject application under any particular provision of Title 35 of the United States Code.

\*These references are not enclosed as they were provided in parent application 08/162,376 and are already of record. (37 CFR §1.98(d)).

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